



PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY
(Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

Translation

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| Applicant's or agent's file reference C1-A0306P | FOR FURTHER ACTION See Form PCT/IPEA/416 | |
| International application No. PCT/JP2004/004331 | International filing date (day/month/year) 26 March 2004 (26.03.2004) | Priority date (day/month/year) 28 March 2003 (28.03.2003) |
| International Patent Classification (IPC) or national classification and IPC C07K 16/18, A61K 39/395, A61P 35/00, 43/00 // C12P 21/08, C12N 15/00 | | |
| Applicant CHUGAI SEIYAKU KABUSHIKI KAISHA | | |

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|---|--|
| <p>1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.</p> <p>2. This REPORT consists of a total of <u>5</u> sheets, including this cover sheet.</p> <p>3. This report is also accompanied by ANNEXES, comprising:</p> <p>a. <input type="checkbox"/> (sent to the applicant and to the International Bureau) a total of _____ sheets, as follows:</p> <p><input type="checkbox"/> sheets of the description, claims and/or drawings which have been amended and are the basis of this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).</p> <p><input type="checkbox"/> sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box.</p> <p>b. <input checked="" type="checkbox"/> (sent to the International Bureau only) a total of (indicate type and number of electronic carrier(s)) <u>DISC 1</u>, containing a sequence listing and/or tables related thereto, in computer readable form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).</p> | |
| <p>4. This report contains indications relating to the following items:</p> <p><input checked="" type="checkbox"/> Box No. I Basis of the report</p> <p><input type="checkbox"/> Box No. II Priority</p> <p><input type="checkbox"/> Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability</p> <p><input type="checkbox"/> Box No. IV Lack of unity of invention</p> <p><input checked="" type="checkbox"/> Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement</p> <p><input type="checkbox"/> Box No. VI Certain documents cited</p> <p><input type="checkbox"/> Box No. VII Certain defects in the international application</p> <p><input type="checkbox"/> Box No. VIII Certain observations on the international application</p> | |

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|--|--|
| Date of submission of the demand 26 March 2004 (26.03.2004) | Date of completion of this report 17 December 2004 (17.12.2004) |
| Name and mailing address of the IPEA/JP | Authorized officer |
| Facsimile No. | Telephone No. |

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.

PCT/JP2004/004331

Box No. I Basis of the report

1. With regard to the language, this report is based on the international application in the language in which it was filed, unless otherwise indicated under this item.

- ☐ This report is based on translations from the original language into the following language _____, which is language of a translation furnished for the purpose of:
- ☐ international search (under Rules 12.3 and 23.1(b))
- ☐ publication of the international application (under Rule 12.4)
- ☐ international preliminary examination (under Rules 55.2 and/or 55.3)

2. With regard to the elements of the international application, this report is based on *(replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report)*:

- ☒ The international application as originally filed/furnished
- ☐ the description:
 pages _____, as originally filed/furnished
 pages* _____ received by this Authority on _____
 pages* _____ received by this Authority on _____
- ☐ the claims:
 pages _____, as originally filed/furnished
 pages* _____, as amended (together with any statement) under Article 19
 pages* _____ received by this Authority on _____
 pages* _____ received by this Authority on _____
- ☐ the drawings:
 pages _____, as originally filed/furnished
 pages* _____ received by this Authority on _____
 pages* _____ received by this Authority on _____
- ☒ a sequence listing and/or any related table(s) – see Supplemental Box Relating to Sequence Listing.

3. ☐ The amendments have resulted in the cancellation of:

- ☐ the description, pages _____
- ☐ the claims, Nos. _____
- ☐ the drawings, sheets/figs _____
- ☐ the sequence listing (*specify*): _____
- ☐ any table(s) related to sequence listing (*specify*): _____

4. ☐ This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).

- ☐ the description, pages _____
- ☐ the claims, Nos. _____
- ☐ the drawings, sheets/figs _____
- ☐ the sequence listing (*specify*): _____
- ☐ any table(s) related to sequence listing (*specify*): _____

* If item 4 applies, some or all of those sheets may be marked "superseded."

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.

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Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

| | | | |
|-------------------------------|--------|------------|-----|
| Novelty (N) | Claims | 1-15 | YES |
| | Claims | | NO |
| Inventive step (IS) | Claims | 1-4, 8-10 | YES |
| | Claims | 5-7, 11-15 | NO |
| Industrial applicability (IA) | Claims | 1-15 | YES |
| | Claims | | NO |

2. Citations and explanations (Rule 70.7)

Documents

Document 1: Human Intestinal H^+ /Peptide Cotransporter, (R. Liang, et al.), J. Biol. Chem., 1995, Vol. 270, No. 12, pages 6456-6463

Document 2: Molecular Cloning of PEPT 2, a New Member of the H^+ /Peptide Cotransporter Family, from Human Kidney, (W. Liu, et al.), Biochimica et Biophysica Acta, 1995, Vol. 1235, pages 461-466

Document 1 describes the base sequence of DNA to code for PepT1, a peptide transporter derived from humans.

Document 2 describes the base sequence of DNA to code for PepT2, a peptide transporter derived from humans.

Claims 1-4 and 8-10

If the base sequence of DNA to code for a protein is known, it was also a known matter prior to the priority date of the present application that the protein can be manufactured by a method of growing a transformant where the said DNA is introduced, etc., and antibodies can be created with the said protein as an immunogen, and that the antigens to inhibit the activity of the said protein can be searched for and obtained from among the above-mentioned antibodies.

Accordingly, a person skilled in the art could have easily produced human PepT1 protein by means of a method of growing a transformant where DNA to code for human PepT1 is introduced, etc., based on the description of the base sequence of such DNA in document 1, and searched for and obtained antibodies capable of inhibiting the activity of PepT1, i.e., inhibiting the transportation activity of PepT1, from among antibodies created with such protein as an immunogen.

In addition, it is not considered that the constitution of the subject matters of the above claims produces a particularly significant effect.

Accordingly, the subject matters of the above claims could have been created based on the descriptions in document 1 and the common technical knowledge before the priority date of the present application by a person skilled in the art, and so do not appear to involve an inventive step.

For the scope of the subject matters of the above claims where PepT2 is concerned, a person skilled in the art could also have easily conceived of it based on the descriptions in document 2 and the common technical knowledge before the priority date of the present application for the same reason as discussed above, and those subject matters do not appear to involve an inventive step.

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Supplemental Box Relating to Sequence Listing

Continuation of Box No. 1, item 2:

1. With regard to any nucleotide and/or amino acid sequence disclosed in the international application and necessary to the claimed invention, this report was established on the basis that of:
- a. type of material
 - ☒ a sequence listing
 - ☐ table(s) related to the sequence listing
 - b. format of material
 - ☐ in written format
 - ☒ in computer readable form
 - c. time of filing/furnishing
 - ☐ contained in the international application as filed
 - ☒ filed together with the international application in computer readable form
 - ☐ furnished subsequently to this Authority for the purpose of search and/or examination
 - ☐ received by this Authority as an amendment* on _____
2. ☒ In addition, in the case that more than one version or copy of a sequence listing and/or table(s) relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.
3. Additional comments:

** If item 4 in Box No. 1 applies, the listing and /or table(s) related thereto, which form part of the basis of the report, may be marked "superseded".*

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Supplemental Box

In case the space in any of the preceding boxes is not sufficient.

Continuation of: V

Claims 5-7 and 11-15

As mentioned above, a person skilled in the art could have easily obtained antibodies capable of inhibiting the transportation activity of peptide transporters PepT1 and PepT2.

However, a person skilled in the art could not have easily conceived of the idea of using such antibodies for restraining the growth of cells or as an anticancer agent, even with the common technical knowledge before the priority date of the present application.

Accordingly, the subject matters of the above claims appear to involve an inventive step in view of the descriptions in documents 1 and 2, and the common technical knowledge before the priority date of the present application.